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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,022	03/06/2007	Petter Bjorquist	056291-5280	8143

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EXAMINER	
HA, JULIE	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,022	BJORQUIST ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary amendment filed on May 04, 2007 is acknowledged. Claim 22 has been added. Claims 1-22 are pending in this application.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 5-6, 16-17 and 22, drawn to a method for the treatment or prophylaxis of a disease or medical condition wherein inhibition of carboxypeptidase U is beneficial, method comprising administering to a warm-blooded animal in need thereof an effective amount of a compound of formula (I).

Group 2, claim(s) 2-4, 7-15 and 18, drawn to a compound of formula (I).

Group 3, claim(s) 19, drawn to a compound of formula (VII).

Group 4, claim(s) 20, drawn to a method for preparing a compound of formula (VII), which comprises treating a compound of formula (VI) with a peptide coupling agent in the presence of a non-nucleophilic base in a polar aprotic solvent, and then removing the protecting group.

Group 5, claim(s) 21, drawn to a method for preparing a compound of formula (I) which comprises reacting a compound of formula VII with a compound of formula VIII.

2. The inventions listed as Groups 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the method claims the MPEP states the following: Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (PCT Rule 6.4). The examiner should bear in mind that a claim may also contain a

reference to another claim even if it is not a dependent claim as defined in PCT Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, "Apparatus for carrying out the process of Claim 1 ...," or "Process for the manufacture of the product of Claim 1 ..."). Similarly, a claim to one part referring to another cooperating part, for example, "plug for cooperation with the socket of Claim 1 ...") is not a dependent claim (see MPEP 1850). Therefore, the method claims are in a different category: method of using the products and method of preparing the compounds of formula (I) and (VII). Therefore, these inventions lack unity of invention.

Rejoinder

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

4. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

6. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

7. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

8. **Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the**

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of Species

9. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different compounds of formula (I) due to different variables;

Different disease or medical conditions: thrombosis or hypercoagulability in blood or tissues, atherosclerosis, fibrotic conditions (genus), inflammatory diseases (genus), a condition which benefits from maintaining or enhancing bradykinin levels in the body of a mammal (genus);

Different peptide coupling agent;

Different non-nucleophilic base;

Different polar aprotic solvent;

Different protecting group;

Different compound of formula (VII) due to different variables;

Different compound of formula (VI) due to different variables;

Different compound of formula (VIII) due to different variables.

10. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

11. If Group 1 or 2 or 5 is elected, Applicant is required to elect a single disclosed species of a compound of formula (I), wherein all of the variables are elected to arrive at a single disclosed species of compound of formula (I). If Group 2 is elected, Applicant is further required to elect a single disclosed species of warm blooded animal, and the disease or disorder to be treated (Please note: some of the disease or disorders are identified as a genus by the Examiner. For an election of species to be complete, Applicant is required to elect a single disclosed species. Any election to a genus would not be a complete response). If Group 3 is elected, Applicant is required to elect a single disclosed species of a compound of formula VII, wherein all of the variables are elected to arrive at a single disclosed species of compound of formula (VII). If Group 4 is elected, Applicant is required to elect a single disclosed species of compound VI, PG1 (protecting group), peptide coupling agent, non-nucleophilic base, and a polar aprotic solvent. If Group 5 is elected, Applicant is further required to elect a single disclosed species of formulas (VII) and (VIII), wherein all of the variables are elected to arrive at a single disclosed species of formulas (VII) and (VIII).

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the

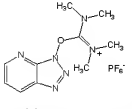
elected species. MPEP § 809.02(a).

13. The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-22.

The following claim(s) are generic: None.

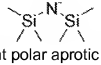
14. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Different compound of formula (I) are patentably independent and distinct due to their different structures due to different variables. For example a compound of formula (I) wherein R^2 is(6-aminopyridin-3-yl)methyl would not necessarily lead to a compound wherein R^2 is heteroaryl(C_{1-4})alkyl substituted with NH_2, leading to independent searches. Different disease or medical conditions are patentably independent and distinct due to their different mechanisms and different cells involved. For example, atherosclerosis is a disease affecting arterial blood vessels; rheumatoid arthritis is an inflammatory disease that most commonly affects the joints. A patient suffering from atherosclerosis would not necessarily suffer rheumatoid arthritis. Further, search for one would not necessarily lead to the other. Different peptide coupling agents are patentably independent and distinct due to their different structures. For example, HATU has the structure



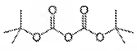
and HOAT has the structure

. Further, search for one would not necessarily lead to the other. Different non-nucleophilic bases are patentably independent and distinct due to their different structures. For example, lithium diisopropylamide has the structure

while potassium bis(trimethylsilyl)amide has the structure



. Further, search for one would not necessarily lead to the other. Different polar aprotic solvents are patentably independent and distinct due to

their different structures. For example, DMF has the structure  and acetone (ketone) has a structure  . Further, search for one would not necessarily lead to the other. Different peptide protecting group is patentably independent and distinct due to their different structures. For example, Di-tert-butyl dicarbonate (t-BOC) has the structure  and an acetyl protecting group has the structure  . Further, search for one would not necessarily lead to the other. Different compounds of formula (VII), (VIII) and (VI) are patentably independent and distinct from each other due to their different structures due to different variables. Further, search for one would not necessarily lead to the other.

15. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

16. The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

17. **Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of**

record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

18. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. H./
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654